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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,183	03/30/2001	Paul C. Reardon	01801-P0026A	9166

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

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DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,183

Applicant(s)

REARDON, PAUL C.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25-30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-30, 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed October 01, 2002 has been received. Claims 24 and 31 have been canceled. Claims 1-23, 25-30 and 32-40 are pending.
2. The text of those US Codes not found in this office action may be found in a previous office action.
3. All rejections not reiterated herein below are withdrawn in light of the amendment to the claims.

Claim Rejections - 35 USC §103

4. Claims 1-8, 10-21, 23, 25-29, 32, 39 and 40 are rejected under 35 USC § 103(a) as being unpatentable over May (GB 2,204,398) in view of Massaro (US 5,141,877) for reasons of record in the previous office action, paper no. 5.
5. Claims 9, 22 and 30 are rejected under 35 USC § 103(a) as being unpatentable over May in view of Massaro as applied to claims 1-8, 10-21, 23, 25-29, 32, 39 and 40 above, and further in view of Brizgy et al (US 5,807,752) for reasons of record in the previous office action, paper no. 5.
6. Claims 33-38 are rejected under 35 USC § 103(a) as being unpatentable over May in view of Massaro as applied to claims 1-8, 10-21, 23, 25-29, 32, 39 and 40 above, and further in view of Deutsch et al (US 4,094,647) for reasons of record in the previous office action, paper no. 5.

Response to Arguments

7. Applicant's arguments filed October 01, 2002 have been fully considered but are not deemed to be persuasive.

Applicant argues that May differs from the instant invention in failing to teach the step of "providing a conjugate pad", thus May cannot anticipate the instant invention. This argument has been fully considered but is deemed not to be persuasive. The instant conjugate pad is nothing more than a pad or zone having labeled binding partner for the analyte. Such a pad is taught throughout the teachings of May. May teaches a first zone comprising labeled specific binding partner for binding to the analyte at page 7, lines 30-33; or labeled reagent incorporated elsewhere within the device such as in the sample collection member (page 7, lines 19-21.) Although the zone or pad bearing the labeled reagent is not designed as a conjugate pad, it is seen to be the same with the instant conjugate pad because they both serve the same function and carry the same reagent. Nothing ~~is~~ in the instant conjugate pad distinguishes it from the labeled reagent zone taught by May.

Applicant argues that the combination of May and Massaro is improper because there is no suggestion or motivation in either reference to combine their teachings. Specifically, applicant argues that because Massaro teaches a multi-step method for detecting Bence Jones proteins, a combination of May and Massaro would result in the urine sample being pretreated through centrifugation and the addition of antiserum reagent directly to the sample before being tested.

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These arguments have been fully considered but are not persuasive. May teaches the convenience of a one step assay and a device for performing such an assay. May teaches that their device may be modified to detect a wide variety of analytes by choice of appropriate specific binding reagents (page 17, lines 4-6). May also teaches that a one step assay provides the advantages of a diagnostic test device suitable for home use that is quick and convenient to use, and requires the user to perform as few actions as possible. The device of May optimizes a diagnostic assay by eliminating the extra steps of washing and isolating/centrifuging a sample before the assay is performed. A skilled artisan would have had a reasonable expectation of success in modifying the device of May to detect analytes such as Bence Jones proteins as taught by Massaro. May teaches that either antigen or antibody may be used as the capture and labeled reagent depending of the analytes being detected, and Massaro teaches that Bence Jones proteins may be detected using an antigen-antibody reaction, and that the detection of Bence Jones proteins in the urine is advantageous because it provides a diagnosis of the existence of a pathological condition.

Applicant argues that the instant claims require the detection of free light chains and classes thereof and that this limitation is not taught by either May or Massaro for use in a test strip.

This argument has been fully considered but is not deemed to be persuasive. May teaches a chromatographic test strip for detecting various analytes in a urine sample, and Massaro teaches that Bence Jones protein, (i.e. free light chains of immunoglobulins) may be detected in a urine sample. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of May to detect the free light chains of Igs such as taught by Massaro for the advantages discussed in the previous office action and reiterated above.

Applicant argues that since Brizgy fails to teach the step of providing a conjugate pad, the claims are not obvious over the combination of May, Massaro and Brizgy.

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This argument has been fully considered but is not deemed to be persuasive. Brizgy is cited for its teaching of Protein A as a capture reagent. The step of providing a conjugate pad is taught by May as discussed above.

Applicant argues that Deutsch also fail to make obvious the instant claims because Deutsch fails to teach the step of providing a conjugate pad.

This argument has been fully considered but is not deemed to be persuasive. Deutsch is cited for its teaching of a test tube for holding a liquid. The step of providing a conjugate pad is taught by May as discussed above.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

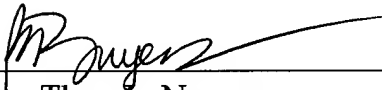
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703)

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308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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December 19, 2002